# CLEAN: What techniques for hand sanitation are associated with favorable food safety outcomes?

#### Conclusion

Strong, clear and consistent evidence shows that hand washing with plain soap for 20 to 30 seconds followed by proper hand drying is an effective hand hygiene technique for preventing cross-contamination during food preparation. Strong, clear and consistent evidence shows that alcohol-based, rinse-free hand sanitizers are an adequate alternative when proper hand washing with plain soap is not possible.

**Grade: Strong** 

Overall strength of the available supporting evidence: Strong; Moderate; Limited; Expert Opinion Only; Grade not assignable For additional information regarding how to interpret grades, click here

#### **Evidence Summary Overview**

A total of 17 studies were reviewed regarding in-home techniques for hand washing that are associated with favorable food safety outcomes such as reduced subsequent risk of home-based food-borne illnesses. Three received (+) quality ratings (two randomized controlled trials (RCT), one meta-analysis) and 14 received Ø quality ratings (two systematic review studies, one meta-analysis, three RCTs, one set of randomized controlled experiments, two prospective cohort studies, one before-and-after study, one cross-sectional and before-and-after study, three non-randomized trials). Studies were conducted in schools and other community settings as well as in homes and under laboratory simulation conditions.

#### School and Other Community Settings: Meta-analysis

Aiello et al, 2008 conducted a meta-analysis to examine the impact of hand hygiene interventions on gastrointestinal and respiratory illness. Of the 30 studies included, 67% were conducted in developed countries, 63% were conducted in child-care centers or schools and 59% targeted children under five years old. Compared with non-intervened controls, washing with non-antibacterial soap and water together with education was the most beneficial intervention for reducing the risk of gastrointestinal (GI) RR=0.61; 95% CI:0.43,0.88, N=6 studies) and respiratory illness (RR=0.49; 95% CI:0.40,0.61, N=1 study). Education alone was not as effective and antibacterial soaps did not reduce the risk further. Alcohol based hand sanitizers (ABHSs) were less effective than non-antibacterial soap at reducing GI risk. This meta-analysis strongly suggests that in settings where non-antibacterial soap is available, ABHSs or antibacterial soaps are not needed for routine hand sanitation.

# **School Settings**

Schools have been identified as potential candidates for promotion of hand hygiene through rinse-free antimicrobial hand sanitizers. Meadows and Le Saux (2004) conducted a systematic review of six controlled trials, three of which were RCTs, conducted in US schools to assess the impact of rinse-free anti-microbial hand sanitizers on school absenteeism due to respiratory and/or GI illness. Four of the six studies used alcohol-based and two used benzalkonium chloride based hand gel sanitizers. All six studies found a significant impact of the rinse-free anti-microbial hand sanitizers at reducing school absenteeism due to communicable diseases (absenteeism reduction range: 20%-56%). Findings should be interpreted with caution due to study design and statistical analysis limitations in the studies reviewed. Tousman et al. (2007) found that a hand washing education program among second graders reduced school absenteeism and was associated with lower microbial loads in hands, compared to the reference group formed by first graders in the same schools. Sandora et al. (2008) found that providing school classrooms with alcohol-based hand sanitizers and quarternary ammonium surface wipes was linked with reduced student absenteeism due to GI but was not associated with reduced incidence of respiratory infections. White et al. (2005) found that provision of ABHSs among college students was associated with a lower incidence of respiratory infections. In their study, they assigned students in two dorms to be exposed to a hand washing campaign that emphasized respiratory infection prevention. In these dorms alcohol gels were made available at the bathroom and dining room and students were provided with them for their rooms and in travel packs. Two additional dorms served as controls. In contrast, Vessey et al. (2007), in their randomized crossover trial comparing the efficacy of a hand sanitizer to standard hand washing in reducing illness and subsequent absenteeism in school-age children, found that no significant differences were noted between the groups (soap and water vs. hand sanitizer), indicating that the number of student absences was not appreciably affected by hand-cleansing technique used. However, those authors noted that hand sanitizers are a viable alternative to routine hand cleansing using soap and water (Vessey et al. 2007). Brown et al. (2007) found among college students, that plain and anti-microbial liquid hand cleansers as well as ABHS reduced hand bacteria count after a 20 second hand wash or rubbing. However, counts were reduced significantly more with ABHS.

# **Home Settings**

Sandora et al, 2005 conducted an RCT where the intervention group received alcohol-based hand sanitizers for use at home and

the control group received nutrition education only. The study targeted families with young children attending day care centers. Findings showed that the intervention was effective at reducing the incidence of secondary GI, but not respiratory infections. They suggest that ABHSs represent a reasonable option when plain soap and hand washing facilities are not readily available. Larson et al, (2004) concluded from their Latino household randomized trial that providing a bundle of antibacterial home cleaning and handwashing products, including liquid triclosan-containing soap, did not reduce the risk of respiratory and viral GI infections. By contrast Lee at al, (2005) concluded that alcohol-based hand gels protected families against transmission of respiratory, but not GI, infections in the home. This observational prospective study was based on families with children between six months and five years of age.

#### Hand Hygiene and Cross-contamination

## Laboratory and computer simulation studies:

Haas et al, 2005 computer simulation concluded that alcohol based but not triclosan-based hand sanitizers are more effective than sanitizers not containing anti-microbials at reducing risk of transmission of *E. coli* pathogenic strains from ground beef to mouth. Simulation was based on a quantitative microbial risk assessment meta-analysis. By contrast, Schaffner and Schaffner (2007) found in their laboratory and computer simulation study that the effectiveness of an ABHS to prevent transfer of Enterobacter aerogenes from frozen hamburger beef patties (inoculated with this non-pathogenic strain used as a surrogate for *Escherichia coli* O157:H7) to ready to lettuce was similar to the one previously found by the same group for hand washing with soap or glove use and that all interventions (handwashing, use of gloves or sanitizer) were more effective than no intervention at all. In contrast with Aiello's et al, (2007) findings, Fischler et al, (2007) concluded from a series of four randomized experiments that triclosan-containing hand sanitizer was more effective than non-antimicrobial soap at reducing loads Shigella flexenerei and *Escherichia Coli* and their transfer rates to freshly cut cantaloupes, after inoculating them in the participants' hands.

#### **Home Kitchen**

**Dharod et al, 2009** found that the presence of *S. aureus* in chicken and salad during meal preparation, as well as in kitchen, counters or cutting boards and sink was positively associated with the presence of this bacteria in the hands of meal preparers at baseline. Likewise baseline coliform count on the counter or cutting board was positively associated with baseline coliform count in participants' hands. Coliform count in chicken increased significantly during meal preparation among meal preparers that tested positive but not among those who tested negative for coliforms in their hands at baseline. These findings suggest that proper hand hygiene is essential for prevention of cross-contamination in the home kitchen.

#### **Antibacterial Soaps and Microbial Antibiotic Resistance**

Per two studies, soaps with antimicrobial additives are not needed for proper hand hygiene at home and should be avoided due to possible microbial resistance to antibacterials associated with their long-term use (Aiello et al, 2007; Thorrold et al, 2007). Aiello et al, (2007) conducted asystematic review (N=27 studies) to assess the efficacy of antibacterial soaps and whether antibacterial soap is associated with microbial antibiotic resistance. Of the four randomized community trials included, three were conducted in the US and one in Pakistan, all of them included families with children under four years of age. None of the studies found a benefit of triclosan/triclocarban-containing soap over non-antibacterial soap at reducing the incidence of infectious diseases over a one year period. Further studies are needed to find out the effectiveness of triclosan/triclocarban-containing soap among the elderly and other immunocompromised individuals. Whereas none of three population-based studies with a one-year follow-up period find antibiotic resistance, seven out of 11 laboratory based studies did find antibiotic resistance associated with the use of triclosan-containing soap. Thorrold et al, (2007) concluded that incorrect usage of antimicrobial household detergents may result in selection of bacteria with reduced susceptibility to both antibiotics and anti-microbials. In contrast, Aiello et al, (2004) concluded that the absence of a statistically significant association between elevated triclosan MICs and reduced antibiotic susceptibility may indicate that such a correlation does not exist or that it is relatively small among the isolates that were studied. However, those authors also indicated that a relationship may emerge after longer-term or higher-dose exposure of bacteria to triclosan in the community setting (Aiello et al, 2004).

#### **Evidence Summary Paragraphs**

**Aiello et al, 2004** (positive quality), an RCT conducted in the US, examined hand cultures from individuals randomized to using either antibacterial or non-antibacterial cleaning and hygiene products for a one-year period. Antibacterial products included a hand soap containing 0.2% triclosan. At baseline, there were 238 households randomized and 224 completed the study. There was no statistically significant association between triclosan MICs and antibiotic susceptibility.

**Aiello et al, 2007** (neutral quality), a systematic review of 27 international studies examining either the effectiveness of triclosan or the risks of antibiotic resistance associated with exposure to triclosan, concluded that soaps containing triclosan within the range of concentrations commonly used in the community setting (0.1% to 0.45% weight/volume) were no more effective than plain soap at preventing infectious illness symptoms and reducing bacterial levels on hands. In addition, several laboratory studies reported evidence of triclosan-adapted cross-resistance to antibiotics among different species of bacteria.

**Aiello et al, 2008** (positive quality), a meta-analysis of 30 international studies published between 1960 and 2007, examined the effect of hand-hygiene interventions on rates of GI and respiratory illnesses. Improvements in hand hygiene resulted in reductions in gastrointestinal illness of 31% (overall rate ratio=0.69, 95% CI: 0.58, 0.81) and reductions in respiratory illness of 21% (overall

rate ratio=0.79, 95% CI: 0.66, 0.95). The most beneficial intervention was hand-hygiene education and non-antibacterial soap use (rate ratio=0.61, 95% CI: 0.43, 0.88); use of antibacterial soap showed little added benefit when compared with use of non-antibacterial soap.

Brown et al, 2007 (neutral quality), a cross-sectional and before-and-after study, determined public attitudes about available hand cleansers through a telephone survey of 40 participants and written survey of 60 college students, as well as the effectiveness of three hand cleansers (liquid hand soap, antibacterial soap and alcohol gel) in reducing bacteria on hands in 90 college students. Most respondents believed that regular hand soaps were not as effective as antibacterial soaps in reducing bacteria on hands, but all three hand cleansers reduced bacteria on hands when a 20 second hand wash procedure was followed. There were NS differences in post-hand wash relative colony numbers for regular and liquid antibacterial hand cleansers, however, alcohol gel reduced relative colony numbers significantly more than either regular or antibacterial cleanser (P<0.05).

**Dharod et al, 2009** (neutral quality) an observational prospective cohort conducted in the US which examined the association of microbial contamination of meal preparers' hands with microbial status of food and kitchen and utensil surfaces during preparation of a "Chicken and Salad" meal. An observational home food safety assessment was conducted with 60 Puerto Rican women in which participant's hands were tested to estimate total bacterial and coliform counts and the presence of Campylobacter, Salmonella, Listeria and *S. aureus* before and after preparing a "Chicken and Salad" meal; microbiological testing was also conducted on samples from kitchen or utensil surfaces and food ingredients before and during meal preparation. Authors found that aureus in chicken and salad during meal preparation and in the kitchen, counters or cutting boards, and sink was positively associated with *S. aureus* on participants' hands at baseline (P<0.05); baseline coliform count on the counter or cutting board and sink was significantly higher when participants' hands tested positive for coliform at baseline; and coliform count in chicken increased significantly during meal preparation among meal preparers that tested positive but not among those who tested negative for coliform on their hands at baseline. Authors concluded that meal preparer's hands can be a vehicle of pathogen transmission during meal preparation.

**Fischler et al, 2007** (neutral quality), a set of randomized controlled experiments conducted in the US, evaluated the effectiveness of a commercially available anti-microbial hand soap containing triclosan as the active antimicrobial ingredient and a plain non-medicated hand wash (plain soap) at reducing bacteria on hands following a 15- or 30-s hand wash and examined the subsequent transfer of the surviving bacteria from the washed hands to a ready-to-eat food item, freshly cut cantaloupe melon balls. Seven to 13 subjects >18 years of age were randomly assigned to receive a single hand washing treatment with either anti-microbial hand soap or a plain soap following hand contamination with S. flexneri or *E. coli* as part of a series of four experiments were performed using different soaps and different lathering times. In all the experiments, the anti-microbial hand soap was significantly better than plain soap and water at eliminating bacteria on hands and subsequently at reducing the transfer of bacteria from hands to food; the anti-microbial soap achieved 3.84- and 3.29-log reductions vs. *E. coli* after a 15-s wash and 3.31- and 2.83-log reductions vs. S. flexneri after a 30-s wash, whereas the plain soap failed to achieve a 2-log reduction against either organism, regardless of the wash time; significantly fewer bacteria were transferred to the melon balls from hands washed with anti-microbial soap than from hands washed with plain soap. Authors indicate that the data demonstrate there is a greater potential to reduce the transmission and acquisition of disease through the use of an anti-microbial hand wash than through the use of plain soap.

Haas et al, 2005 (neutral quality), a meta-analysis of five studies and quantitative microbial risk assessment, estimated the benefits resulting from the use of hand cleansing products (e.g., soaps) containing anti-microbial ingredients using a model for the scenario of hand contact with ground beef during food preparation, considering transference of bacteria to the hands, removal and inactivation by handwashing and subsequent transference from the hands to the mouth. There was a reduction in risk from the use of any hand washing protocol as compared to no hand washing. Anti-microbials reduced the risk of infection and illness, however, benefits from the use of triclosan-containing products were less than from the use of products in which alcohols or chlorhexidine were active ingredients.

Larson et al, 2004 (positive quality), an RCT conducted in the US, examined rates of infectious disease symptoms from households randomized to using either antibacterial or non-antibacterial cleaning and hygiene products for 48 weeks. At baseline, there were 238 households randomized and 224 completed the study. Rates of any infectious disease symptoms did not differ between intervention and control groups. That is, providing a bundle of antibacterial home cleaning and handwashing products, including liquid triclosan-containing soap, did not reduce the risk of respiratory and viralGI infections.

Lee et al, 2005 (neutral quality), an observational, prospective cohort study conducted in the US, assessed occurrence of respiratory and gastrointestinal illnesses in families with children enrolled in child care and studied predictors of lower rates of illness transmission in the home. A total of 261 families were enrolled in the study and 215 families (82%) completed at least four weeks of illness transmission data. Only two-thirds of respondents believed that contact transmission was important in the spread of cold and fewer than half believed that it was important in the spread of stomach flus. Reported use of alcohol-based hand gels reduced transmission of respiratory illness among family members.

Meadows and Le Saux, 2004 (neutral quality), a systematic review of six studies examining whether antimicrobial rinse-free hand sanitizer interventions are effective in preventing illness-related absenteeism in elementary school children. All studies found a statistically significant effect of the anti-microbial rinse-free hand gel; trials varied with respect to intervention, including germ and hygiene education that was provided with sanitizer; but due to the large amount of heterogeneity and low quality of reporting, no pooled estimates were calculated. The authors noted that the available evidence for the effectiveness of antimicrobial rinse-free hand sanitizer in the school environment is of low quality.

Sandora et al, 2005 (neutral quality), a cluster, RCT conducted in the US, determined whether a multi-factorial campaign centered on increasing alcohol-based hand sanitizer use and hand-hygiene education reduces illness transmission in the home. A total of 292 families were randomized to a treatment group or a control group; all families were included in the intent-to-treat analysis. Those in the treatment group received a supply of hand sanitizer to use in the home and bi-weekly hand-hygiene educational materials at home for a five-month period, while those in the control group received bi-weekly education about a healthy diet and were asked to not use hand sanitizer during the same period. The secondary GI rate was significantly lower in intervention families compared with control families (incidence rate ratio: 0.41, 95% CI: 0.19, 0.90), while the overall rate of secondary respiratory illness was not significantly different between groups.

Sandora et al, 2008 (neutral quality), an RCT conducted in the US, assessed the effectiveness of a multi-factorial infection-control intervention, including alcohol-based hand sanitizer and surface disinfection, in reducing absenteeism caused by GI and respiratory illnesses among elementary school students. A total of 285 third, fourth and fifth grade students participated in study in which clustered randomization was used to assign classrooms to intervention or control groups and randomization was stratified by team size; children and teachers used hand sanitizer and surface disinfection, respectively and number and reason for absences was recorded. Compared with control group, unadjusted absenteeism rate for GI illness was significantly lower in the intervention group (rate ratio: 0.86 [95% CI: 0.79-0.94]; P<0.01); after adjusting for race, health status, family size, and current hand-sanitizer use in home, absenteeism rate for GI illness remained significantly lower in the intervention group compared with control group (rate ratio: 0.91 [95% CI: 0.87-0.94]; P<0.01).

Schaffner and Schaffner, 2007 (neutral quality), a before and after study (and computer simulations) conducted in the US, evaluated the effectiveness of an alcohol-based hand sanitizer on hands contaminated with a non-pathogen surrogate for *E. coli* O157:H7, where the source of bacteria was frozen hamburger patties. Thirty two subjects (12 males, 20 females) handled nine frozen beef patties at least three times with microbiological sampling of one hand after pattie handling, then sanitization of both hands, then microbiological sampling of the other hand; computer simulations were also used to perform risk calculations. The average reduction of *E. aerogenes* after using the sanitizer was 2.58 log CFU with  $\pm 0.65$  log CFU variability per hand. None of the interventions (hand washing, gloves, sanitizer) were completely effective, but all interventions were more effective than no intervention at all; that is, the mean reduction for hand washing and the use of gloves or sanitizer was about 3 log (1,000 times) greater than the result for no intervention at all. Authors concluded that use of an alcohol-based hand sanitizing gel is an effective intervention for hands that have been contaminated with *E. coli* O157:H7 from frozen hamburgers.

**Thorrold et al, 2007** (neutral quality), a non-randomized trial conducted in South Africa, examined efflux pump activity in fluoroquinolone and tetracycline resistant Salmonella and *Escherichia coli* samples to see if there was a reduced susceptibility to household antimicrobial cleaning agents. Efflux pump activity was measured by ethidium bromide accumulation assays in eight bacterial strains of Salmonella and nine bacterial strains of *E. coli*. Active efflux of ethidium bromide was associated with antibiotic resistant organisms, suggesting that efflux mechanisms may be responsible for the antibiotic resistance; the authors concluded that incorrect usage of anti-microbial household detergents may result in selection of bacteria with reduced susceptibility to both antibiotics and anti-microbials.

**Tousman et al, 2007** (neutral quality), a non-randomized trial conducted in the US, to determine if a multiple-week learner-centered hand washing program could improve hand hygiene behaviors of second-graders in a public school system. Volunteers went into 19 different classrooms for four consecutive weeks and taught a learner-centered program that included interactive class discussions and activities using GlitterBug® training devices and agar plate materials. There was a statistically significant 34% decrease in the absenteeism rate for students in the intervention group during the third and fourth weeks of the intervention (P=0.027); 58% of the agar plates were cleaner after hand washing (P<0.001); and qualitative data from parents and teachers indicated that a majority of the students were engaging in handwashing behavior.

Vessey et al, 2007 (neutral quality), a randomized crossover trial conducted in the US, compared the efficacy of a hand sanitizer to standard hand washing in reducing illness and subsequent absenteeism in school-age children. Eighteen classrooms of second and third graders from several elementary schools were included in the study (approximately 363 students); for two months, half of the classes from each school used an anti-microbial gel hand sanitizer while the other classes used soap and water, and then the students switched cleaning methods for the following two months. Absentee information was collected by school secretaries through the duration of the study. No significant differences were noted between the groups, indicating that the number of student absences was not appreciably affected by the hand-cleansing technique used. Authors note that obtaining accurate data for absenteeism due to communicable disease was difficult.

White et al, 2005 (neutral quality), a non-randomized trial conducted in the US, evaluated whether a campaign to increase hand hygiene practices, coupled with the introduction of an alcohol-based antibacterial gel, reinforced by messages to continue washing and sanitizing, would decrease the incidence of upper respiratory illnesses (URIs) in a residence hall population on the campus of a major western university. Experimental subjects were exposed to a health campaign to increase awareness of the importance of hand cleanliness in avoiding colds or flu; received free hand sanitizer in their rooms and in travel packs and had access to gel hand sanitizer in dormitory bathrooms and dining room, and then completed, over eight weeks, weekly reports on handwashing and sanitizer use and any experience of cold or flu symptoms. The experimental group had significantly better hand hygiene than control group reflecting a difference in hand-washing behavior and in hand-sanitizer use; increased their knowledge about hand hygiene and the spread of URI from pre to post-study assessments than did controls; and reported 26% fewer illnesses than the control group (illness rate of 20.2% vs. 27.5% in control group across the study, x<sup>2</sup>=19.97, P<0.0001); and women washed their

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Author, Year, Study Design, Class, Rating	Population / Sample Description and Location	Study Design / I & D Variables / Intervention	Results / Behavioral Outcomes / Significance	Limitations
Aiello et al 2007 Study Design: Systematic Review Class: M Rating:	N=27 international studies.	Studies examining either the effectiveness of triclosan or the risks of antibiotic resistance associated with exposure to triclosan.	Soaps containing triclosan within the range of concentrations commonly used in the community setting (0.1% to 0.45% weight/volume) were no more effective than plain soap at preventing infectious illness symptoms and reducing bacterial levels on hands.	Screening of articles and the number of and reasons for excluded studies were not described.  Data extraction process was not described.  Methodologic quality of included studies was not assessed.
			Several laboratory studies reported evidence of triclosan-adapted cross-resistance to antibiotics among different species of bacteria.	
Aiello et al 2008 Study Design: Meta-Analysis Class: M Rating:	N=30 international studies published between 1960 and 2007.	Studies examined the effect of hand-hygiene interventions on rates of gastrointestinal and respiratory illnesses.	Improvements in hand hygiene resulted in reductions in gastrointestinal illness of 31% (overall rate ratio=0.69, 95% CI: 0.58, 0.81) and ↓ in respiratory illness of 21% (overall rate ratio=0.79, 95% CI: 0.66, 0.95).  The most beneficial intervention was hand-hygiene education and non-antibacterial soap use (rate ratio=0.61, 95% CI: 0.43, 0.88); use of	Authors note that in some cases, classification of the intervention was unclear due to multiple components.  For some interventions, only single studies were available.  Heterogeneity was significant in pooled estimates across all studies.  There was evidence of publication bias for
			antibacterial soap showed little added benefit when compared with use of non-antibacterial soap.	gastrointestinal illness outcomes.
Brown et al 2007 Study Design: Cross-Sectional Study, Refore and After	N= 40 telephone survey participants  N= 60 written survey college students  N=90 college students	Surveys determined public attitudes about available hand cleansers, experiment studied effectiveness of three hand cleansers (liquid hand soap, antibacterial soap and alcohol gel) in reducing	Most respondents believed that regular hand soaps were not as effective as antibacterial soaps in reducing bacteria on hands, but all three hand cleansers reduced bacteria on hands	Study was limited by \( \psi \) response rate to the community-based telephone survey.  Participant characteristics are not
Before-and-After Study	on which the experiment was based.	alcohol gel) in reducing bacteria on hands.	reduced bacteria on hands when a 20 second hand	described beyond age, so the generalizability

Class: D Rating:	Location: United States.		followed.  There were NS differences in post-hand wash relative colony numbers for regular and liquid antibacterial hand cleansers, however, alcohol gel \(\psi\) relative colony numbers significantly more than either regular or antibacterial cleanser (P<0.05).	of the results is somewhat unclear.
Dharod JM, Paciello S et al, 2009  Study Design: Observational prospective cohort study  Class: B  Rating:	N=60 Puerto Rican women.  Average age: 40 years.  More than half of participants reported speaking only Spanish at home.  Location: Hartford, Connecticut (United States).	Design:  First day of study:  After purchase, food ingredients were taken to the microbiology laboratory and sampled to determined the presence of any pathogenic species and establish baseline total and coliform counts.  Later the same day, foods were delivered to participant households.  Second visit (one day after first visit):  Household observations were conducted during meal preparation.  Before and after the participant had handled food, participants' hands, food and surface area samples (counter, cutting board, sink and meal preparation utensils) were taken.  Total bacterial and coliform counts and presence of Campylobacter, Salmonella, Listeria, and S. aureus were checked.  A chicken sample was collected after the participant began handling the chicken but before cooking (i.e., after cutting or removing skin and bones and washing).  Lettuce and tomato samples	Participants considering food safety as "very important" were less likely to test positive for <i>S. aureus</i> on hands (P<0.05). <i>S. aureus</i> in chicken and salad during meal preparation and in the kitchen, counters and cutting boards and sink was positively associated with <i>S. aureus</i> on participants hands at baseline (P<0.05).  Baseline coliform count on the counter and cutting board and sink was significantly higher when participants' hands tested positive for coliform at baseline.  Coliform count in chicken increased significantly during meal preparation among meal preparers that tested positive, but not among those who tested negative for coliform on their hands at baseline.	Limitations noted by authors:  1) Regarding interview on third visit:  Only a single question was used to assess food safety attitude and it could not be tested for reliability, although its association with hard microbiological outcomes suggests it is of value.  During the interview, participants were not asked about their understanding of the term "food safety"; thus, the difference in this understanding was not controlled for in the food safety attitude analysis.  2) Social desirability bias:  Study involved direct household observation and collection of samples for microbial analysis during meal preparation may have lead participants to practice better food safety behaviors than usual.  Regarding external validity of the study, Latinas represent a very diverse group and results from one

were were collected after subgroup (Puerto washing, cutting, mixing or Ricans) do not once salad was ready to serve. necessarily apply to others such as Food samples were Mexicans and Central transported to the laboratory and South American at 4°C or less for microbial Latino groups. testing. Third visit (one day after second visit): Meal preparation survey was conducted with the participant, using bilingual outreach workers. **Dependent variables:** Total bacterial and coliform counts and presence of Campylobacter, Salmonella, Listeria and S. aureus on food and surface area samples (counter, cutting board, sink, meal preparation utensils, including knives) after participant handling. **Independent variables:**  Estimated total bacterial and coliform counts on participant's hands • Language spoken at home Age • Place of birth • Monthly income Education level Attitude toward food safety. Fischler GE, Fuls N=7 to 13 subjects. Dependent In all four experiments, the Neither subjects nor JL et al, 2007 variables: Effectiveness was antimicrobial hand soap researchers Age: >18 years. determined by evaluating the was significantly better than were blinded to soap Study Design: difference between the plain soap and water at use. Location: Scottsdale, Randomized baseline and post-wash eliminating bacteria on Arizona (United States). Dial controlled hands and subsequently at \ bacteria recovery counts and Corporation Clinical the difference in the transfer the transfer of bacteria from experiments Studies Department of bacteria to food was hands to food. assisted in the clinical Class: A calculated with the number The anti-microbial soap aspects of the study. of bacteria per 20g of melon achieved 3.84- and 3.29-log (about four melon balls) Small sample size. Rating: ↓ vs. E. coli after a 15-s recovered. wash and 3.31- and 2.83-log Independent variables: ↓ vs. S. flexneri after a 30-s wash, whereas the plain Handwashing treatment with soap failed to achieve a either anti-microbial hand 2-log ↓ against either soap (0.46% triclosan, Dial organism, regardless of the Complete Antibacterial wash time

Foaming Hand Wash) or a plain soap (Kiss My Face Significantly ↓ bacteria were transferred to the Self Foaming Liquid Soap). melon balls from hands Handwashing time (In washed with anti-microbial experiments A and B, the soap than from hands soap was lathered vigorously washed with plain soap. over the hands for 15±2 s, and in experiments C and D, Average log bacteria the soap was lathered for recovery from the melon  $30\pm 2 \text{ s}$ ). balls handled by hands treated with anti-microbial Bacteria tested (either *S*. hand soap was 2.00, 2.36, flexneri or E. coli). 1.97 and 2.27 log. Intervention: Melon balls handled with plain soap-treated hands had Patients were instructed to >3 log bacteria in all four perform a hand washing experiments (a statistically treatment specific to each significant difference type of hand soap tested. (P<0.001, two-tailed) of The soap was dispensed into more than 1.25 log, the subjects cupped dry palm compared with the of one hand and then spread anti-microbial hand wash over the entire surface of the handled melons). hands, including the backs of The number of bacteria that the hands and between the were transferred to the fingers and the lower melon balls following hand one-third of the forearm. washing for both 15 and 30 For the anti-microbial hand s with the anti-microbial soap, two pumps of soap soap was statistically less were dispensed and four than plain soap and water. pumps were used for the plain soap. In experiments A and B, the soap was lathered vigorously over the hands for 15±2 s. and in experiments C and D, the soap was lathered for 30±2 s. After the timed wash, hands were rinsed under running tap water tempered to 40±2°C for 30 s. N=5 international Haas C, Marie J Analysis of hand cleansing There was a ↓ in risk from Search strategies and et al, 2005 studies. the use of any hand search terms not products (e.g., soaps) described. containing anti-microbial washing protocol as compared to no hand Study Design: ingredients using a model for Currently no consensus Meta-Analysis, the scenario of hand contact washing. on appraisal of Quantitative with ground beef during food Antimicrobials reduced the methodologic quality of Microbial Risk preparation, considering risk of infection and illness, risk assessment analysis. transference of bacteria to the Assessment however, benefits from the hands, removal and use of triclosan-containing Class: M inactivation by handwashing products were less and subsequent than from the use of transference from the hands Rating: products in which alcohols

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		to the mount.	or chlorhexidine were active ingredients.	
Larson EL, Lin SX et al, 2004 Study Design: Randomized controlled trial. Class: A Rating:	N=238 households randomized at baseline. N=224 completed the study. Location: United States.	Rates of infectious disease symptoms were examined from households randomized to using either antibacterial or non-antibacterial cleaning and hygiene products for 48 weeks.	Rates of any infectious disease symptoms did not differ between intervention and control groups.	Weekly and monthly contact may have ↑ product use.  There was no guarantee that the participants used the products as directed.
Lee et al 2005  Study Design: Observational, Prospective Cohort Study  Class: B  Rating:	N=261 families enrolled in study. N=215 families (82%) completed at least four weeks of illness transmission data. Location: United States.	The occurrence of respiratory and gastrointestinal illnesses in families with children enrolled in child care was assessed over four weeks, as well as predictors of lower rates of illness transmission in the home.	Only two-thirds of respondents believed that contact transmission was important in the spread of cold.  Fewer than half believed that it was important in the spread of stomach flus.  Reported use of alcohol-based hand gels reduced transmission of respiratory illness.	Outcome measures based on self-report.  Use of alcohol-based hand gels may serve as a proxy for good hand hygiene behaviors.
Meadows E and Le Saux N, 2004  Study Design: Systematic review  Class: M  Rating:	N=6 studies, two of which were randomized (five published studies, one published abstract).  Location: United States.	Dependent variables: Use of anti-microbial, rinse-free hand sanitizer and education on germs and hygiene (provision varied between studies).  Independent variable: Absenteeism due to communicable disease. Studies examined whether anti-microbial rinse-free hand sanitizer interventions are effective in preventing illness-related absenteeism in elementary school children.	All studies found a statistically significant effect of the anti-microbial rinse-free hand gel.  Trials varied with respect to intervention, including germ and hygiene education that was provided with sanitizer.  Due to large amount of heterogeneity and low quality of reporting, no pooled estimates were calculated.  The available evidence for the effectiveness of anti-microbial rinse-free hand sanitizer in the school environment is of low quality.	Four trials reported industrial sponsorship.  Authors noted the following limitations:  1) Scarcity of high quality studies  2) Unpublished, NS trials may exist but were not found in this review  3) No quantitative synthesis could be performed due to differences between the studies (e.g., study designs, population characteristics, intervention characteristics, case definition and primary outcome measure)  4) Only one reviewer was used to do the broad screen and review the two citations identified after

				September 2003. This may have introduced bias.
Newton KM. et al. 1996 Study Design: Retrospective cohort Class: B Rating:	N=238 households randomized at baseline. N=224 completed the study. Location: United States.	Hand cultures were examined from individuals randomized to using either antibacterial or non-antibacterial cleaning and hygiene products for a one-year period.  Antibacterial products included a hand soap containing 0.2% triclosan.	There was no statistically significant association between triclosan MICs and antibiotic susceptibility.	Inclusion/exclusion criteria and recruitment methods not described in this article, but described in Larson et al, 2004.
Sandora TJ, Shih MC et al, 2008 Study Design: Randomized controlled trial Class: A Rating:	N=363 eligible.  N=285 randomly assigned third, fourth and fifth grade elementary school children.  Location: Ohio (United States).	Pependent variables:  Student absences for GI and respiratory illness Bacterial colony counts from designated classroom surfaces Presence of selected viruses on classroom surfaces.  Independent variables: Student use of alcohol-based hand sanitizer and teacher use of quaternary ammonium wipes to disinfect classroom surfaces.  Clustered randomization was used to assign classroom teams to the intervention or control groups.  Randomization was stratified by team size (fourth and fifth grade teams were larger than third grade, so each group contained one larger and two smaller teams).  Children and teachers used hand sanitizer and surface disinfection, respectively.  Teachers disinfected students' desks once daily after lunch.  Students were instructed on proper usage of alcohol-based hand sanitizer and encouraged to use it before and after lunch, after	Compared with control group, unadjusted absenteeism rate for GI illness was significantly lower in the intervention group (rate ratio: 0.86 [95% CI: 0.79-0.94]; P<0.01)  After adjusting for race, health status, family size and current hand-sanitizer use in home, absenteeism rate for GI illness remained significantly ↓ in the intervention group, compared with control group (rate ratio: 0.91 [95% CI: 0.87-0.94]; P<0.01);  Norovirus was the only virus detected on classroom surfaces during the study.  Norovirus was detected on significantly fewer surfaces in the intervention classrooms when compared with controls (9% of intervention classroom samples were positive vs. 29% of control samples; P<0.01).	Authors noted these limitations:  1) This research cannot prove that the demonstrated ↓ in norovirus exposure was the cause of ↓ in absenteeism from GI illness (other GI pathogens could be contributors).  2) Since study design was not factorial, authors could not determine the relative contributions of hand hygiene and surface disinfection to achieving a ↓ in absenteeism from GI illness (Illness definitions were symptom-based, not microbiologically confirmed, so misclassification is possible).  3) Authors made no attempt to verify parental reporting of reason for absence.  4) No diagnostic tests were performed, so authors cannot definitively state that the observed reduction in absenteeism is linked to the observed reduction in environmental

		using the restroom on return to the classroom (hand washing with soap/water occurred in the bathroom) and after any contact with potentially infectious secretions swabs of surfaces were taken by teachers and cultured by researchers.  Number and reason for absences was recorded.		patnogens. 5) Authors did not directly observe usage patterns and cannot address timing of usage in relation to specific exposures. 6) Study took place in a single school, so results may not be generalizable.
Sandora TJ, Tavaras EM et al, 2005 Study Design: Cluster randomized controlled trial Class: A Rating:	N=292 families were randomized to a treatment group or a control group.  All families were included in the intent-to-treat analysis.  Location: United States.	Those in the treatment group received a supply of hand sanitizer to use in the home and bi-weekly hand-hygiene educational materials at home for a five-month period, while those in the control group received bi-weekly education about a healthy diet and were asked to not use hand sanitizer during the same period.  Gastrointestinal and respiratory illness rates were examined.	The secondary gastrointestinal illness rate was significantly ↓ in intervention families, compared with control families (incidence rate ratio: 0.41, 95% CI: 0.19, 0.90), while the overall rate of secondary respiratory illness was NS different between groups.	Illness was based on self-report.  Low participation rates.  Lack of blinding for subjects and data collectors.  Homogenous sample of largely white, high income and high education subjects limits generalizability.
Schaffner D and Schaffner K, 2007 Study Design: Laboratory and computer simulations Class: D Rating:	N=32 University staff members and students (12 males, 20 females). Location: New Bruswick, New Jersey (United States).	<ul> <li>Dependent variables:</li> <li>Δ in concentration of E. aerogenes deposited on hands before/after use of hand sanitizer (for experiments)</li> <li>Concentration of E. coli O157:H7 per lettuce leaf after handling raw hamburgers (for simulations).</li> <li>Independent variables:</li> <li>Sanitizer intervention (for experiments)</li> <li>Other interventions (hand washing, glove use) (for simulations).</li> <li>Intervention: The sanitizer used for the experiment:</li> <li>Applied ~1ml of</li> </ul>	Findings from the experiment  The average transfer rate of <i>E. aerogenes</i> from frozen hamburgers to hands was 1.48%, which corresponds to a 1.83 log CFU ↓ with ±0.70 log CFU variability per hand while the average ↓ of <i>E. aerogenes</i> after using the sanitizer was 2.58 log CFU with ±0.65 log CFU variability per hand.  Findings from the simulation:  The risk estimation for transfer of <i>E. coli</i> O157:H7 to a single piece of lettuce is 10-6 CFU per lettuce leaf.  While none of the interventions (hand washing, gloves, sanitizer)	Authors noted the following limitation:  If the frozen burgers were allowed to thaw (even only at the surface), transfer rates (and risk) might be expected to rise by an order of magnitude, because moisture facilitates microbial transfer (and the investigators noted that most of the subjects had visible debris on their hands after handling the frozen burgers).

		ingredients) on contaminated hands until the participant determined the process was complete (generally <30 seconds)  2) Other interventions (hand washing, glove use) for the computer simulations (based on data presented elsewhere)	intervention at all (mean ↓ for hand washing and the use of gloves or sanitizer was about 3 log (1,000 times) greater than the result for no intervention at all).  The three interventions appear to have similar effectiveness, with an average simulated E. coli O157:H7 concentration of 10-2 CFU per lettuce leaf.  The minimum reduction using gloves or sanitizer was about 2 log greater than that for either no intervention or hand washing.	
Thorrold CA, Letsoalo ME et al, 2007  Study Design: Non-randomized trial  Class: C  Rating:	N=8 bacterial strains of Salmonella and N=9 bacterial strains of <i>E. coli</i> .  Location: South Africa.	Efflux pump activity was measured by ethidium bromide accumulation assays in fluoroquinolone and tetracycline resistant Salmonella and Escherichia coli samples to see if there was a \( \prescript{\subset} \) susceptibility to household antimicrobial cleaning agents.	Active efflux of ethidium bromide was associated with antibiotic resistant organisms, suggesting that efflux mechanisms may be response for the antibiotic resistance.  Authors concluded that incorrect usage of antimicrobial household detergents may result in selection of bacteria with reduced susceptibility to both antibiotics and antimicrobials.	Small sample sizes.
Tousman S, Arnold D et al, 2007  Study Design: Non-randomized trial with concurrent controls  Class: C  Rating:	N=406 first and second grade students enrolled in 19 classrooms in seven schools.  Location: Rockford, Illinois (United States).	Dependent variables:  Parent evaluation via six-item survey to assess child's hand hygiene behavior at home.  Teacher evaluation via five-item survey to assess the value and effectiveness of the program and to elicit suggestions for improvement.  Agar plate data: Staff assessed plates as having "fewer," "more," or an "equal" amount of germs before and after hand washing.  Absenteeism data: Collected	There was a statistically significant 34% ↓ in the absenteeism rate for students in the intervention group during the third and fourth weeks of the intervention (P=0.027).  58% of the agar plates were cleaner after hand washing (P<0.001).  Qualitative data from parents and teachers indicated that a majority of the students were engaging in handwashing behavior.	Limitations noted by authors:  1) Inability to get data on absenteeism due to illness may have confounded the results.  2) ~50% of parents returned the survey, perhaps parents who didn't return the survey did not notice any Δ in their child's hand washing behavior.  3) Only 58% of students had cleaner hands after washing (as determined via agar plates), so more

		out absenteeism due to illness).		skill-building may be necessary.
		Independent variables:		Other:
		<ul> <li>Hand washing</li> <li>Hand hygiene instruction and support.</li> <li>Intervention:</li> <li>Volunteers of a local</li> </ul>		1) Age/maturity characteristics of control group (first grade students) differed compared to intervention group (second grade students)
		handwashing coalition visited schools weekly for four weeks to conduct hygiene education that included open-ended interactive class discussions.  Learning demonstrations and activities, including the use of the GlitterBug® device (UV light/glow product) before/after learning correct		2) Unclear if other characteristics of intervention vs. control subjects were similar at baseline (e.g., use of hand sanitizer in the home; general health).  3) Staff assessment of agar plates seems somewhat subjective.
		hand washing techniques.  Distribution of handouts including hand hygiene coloring sheets, stickers and a completion certificate		somewhat sasjective.
		A summary of key Learning Points at the end of each session and instruction on how students can self-monitor health/hygiene behavior during the week.		
Vessey JA, Sherwood JJ et al, 2007 Study Design: Randomized crossover trial Class: A	N=18 classrooms of second and third graders from several elementary schools included (~363 students).  Location: United States.	Randomized crossover trial in which half of the classes from each school used an anti-microbial gel hand sanitizer for two months while the other classes used soap and water and then the students switched cleaning methods for the following two months.	NS differences were noted between the groups, indicating that the number of student absences was not appreciably affected by the hand-cleansing technique used.	Obtaining accurate data for absenteeism due to communicable disease was difficult.
Rating:		Absentee information was collected by school secretaries through the duration of the study.		
White C et al 2005 Study Design: Nonrandomized Trial	N=430 college students initially enrolled. N=391 completed study (188 in experimental group; 203 in control	Dependent variables:  1) Knowledge, attitudes, perceived behavior about hand hygiene, handwashing, the health benefit of using hand sanitizer	1) Experimental group had significantly better hand hygiene than control group reflecting a difference in hand-washing behavior [t(330)=2.06, P<0.02] and	Partially funded by authors noted these limitations:  1) It was not possible to determine whether the message campaign or

Class: C

Rating:

group).

Age: No specific ages provided; 85.6% college freshman.

88% White,1.7% African American, 4.2% Hispanic or Latino, 2.8% Asian or Pacific Islander.

Location: University of Colorado, Boulder (United States).

- 2) Average frequency of hand washing or anitbacterial gel hand sanitizer use
- 3) Upper respiratory illness (URI) rates
- 4) Absenteeism
- 5) Awareness and perceptions about message campaign.

## Independent variables:

- Health campaign bulletin board messages in hall corridors and outside dining halls
- Health campaign flier messages in bathroom stalls which were changed weekly
- Free Purell hand sanitizer in subjects' rooms and in travel packs
- Gel hand sanitizer in the dormitory bathrooms and hall dining room.

#### Intervention:

A health campaign to increase awareness of the importance of hand washing and hand cleanliness in avoiding colds and the flu.

#### Campaign included:

- Bulletin board messages in hall corridors and outside dining halls
- Flier messages in bathroom stalls which were changed weekly
- Messages progressed from attention getting to knowledge, benefits and persuasion
- Free Purell hand sanitizer in their rooms and in travel packs
- Gel hand sanitizer in the dormitory bathrooms and hall dining room.

[t(367)=12.92, P<0.0001]

- 2) Experimental group ↑ their knowledge about hand hygiene and the spread of URI from pre- to post-study assessments than did controls
- 3) Experimental group reported 26% ↓ illnesses than control group (illness rate for experimental group was 20.2% vs. 27.5% in control group across the study, X2=19.97, P<0.0001) (students were identified as experiencing URI when reported two or more URI symptoms lasting two to three days)
- 4) Women washed their hands more frequently than men [(0.49 vs. 0.40), F(1, 295) = 11.60, P<0.001], but NS difference in use of gel hand sanitizer.

- sanitizer alone would influence illness
- 2) Use of self-report data illness was not verified by medical examination; thus, some students who experienced symptoms may have been classified as having an illness when they were not ill
- 3) Lack of baseline rates of illness in each residence hall did not allow for the determination of whether differences in illness may have resulted from the overall illness rate in each hall
- 4) Likelihood of contracting a URI is influenced by a number of health behaviors and may not just be due to careful hand hygiene which can help students avoid URIs

While no differences in smoking or allergy rates were found between experimental and control groups, smoking slightly \(\gamma\) the occurrence of URI in both groups.

# Research Design and Implementation Rating Summary

For a summary of the Research Design and Implementation Rating results, click here.

#### Worksheets

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